UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE: PRADAXA (DABIGATRAN EXTEXILATE) PRODUCTS LIABILITY LITIGATION	3:12-MD-02385-DRH-SCW **MDL No. 2385**
MARY LOYD BARBAREE and JAMES M. BARBAREE Plaintiffs, vs. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; and BOEHRINGER INGELHEIM INTERNATIONAL GMBH Defendants.	Judge David R. Herndon COMPLAINT AND JURY DEMAND Civil Action No.____________________

COME NOW the Plaintiffs, MARY LOYD BARBAREE and JAMES M. BARBAREE , by and through Plaintiffs' attorneys, brings this action for personal injuries against Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim International GMBH, ("collectively, "Defendants") and for cause therefore would show unto the Court the following:

PARTIES

Plaintiffs

1. Plaintiffs, Mary Loyd Barbaree and James M. Barbaree (hereinafter "Plaintiff" and "Plaintiff's") were, at all relevant times to this action, residents and citizens of Tallapoosa County in Dadeville, Alabama and are natural citizens. Plaintiffs are currently, and were at all times relevant to this action, married and residing together in Tallapoosa County in Dadeville, Alabama.

Defendants

2. Defendant BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. ("Boehringer") is a Delaware corporation which has its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Pursuant to CMO No. 7 dated October 3, 2012 by Honorable Chief Judge David R. Herndon, Defendant BIPI has agreed to accept service by forwarding this Complaint and a Waiver of Service via email to MDLPradaxa@butlersnow.com or by U.S. Mail to Keishunna Randall, Butler, Snow, O'Mara, Stevens & Cannada, PLLC, Post Office Box 6010, Ridgeland, MS 39158-6010.

3. Defendant BOEHRINGER INGELHEIM INTERNATIONAL, GmbH ("Boehringer International") is a foreign corporation with its principal place of business located at Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany. Pursuant to CMO No. 12 dated October 19, 2012 by Honorable Chief Judge David R. Herndon, Defendant Boehringer International has agreed to accept service by forwarding this Complaint and a Waiver of Service via email to vlodato@sillscummis.com or by U.S. Mail to Vincent Lodato, Esq., Sills Cummis & Gross, P.C., One Riverfront Plaza, Newark, New Jersey 07102.

4. At all times relevant to this Complaint, the Defendants were the agents of each other and in doing the things alleged herein, each Defendant was acting within the course and scope of its agency and was subject to and under the supervision of its co-defendants.

JURISDICTION AND VENUE

5. Jurisdiction is proper in this court pursuant to 28 U.S.C. § 1332 for the reason that there is complete diversity of citizenship between Plaintiff and Defendants and the matter in controversy greatly exceeds the sum of seventy-five thousand dollars ($75,000.00), exclusive of interest and costs.

6. This Court has jurisdiction over the non-resident Defendants because they placed a defective product into the stream of commerce and that product caused personal injuries to Plaintiff at Plaintiff's residence in the state of Alabama and cases involving these claims have now been consolidated in this District pursuant to 28 U.S.C. §1407. Defendants have sufficient minimum contacts with the forum state such that they are subject to personal jurisdiction within said district.

7. Venue of this case is proper the Southern District of Illinois pursuant to 28 U.S.C.§1391(a). Venue is further proper under the order on the judicial panel on multidistrict litigation and Case Management Order #7 dated October 3, 2012 by Honorable Chief Judge David R. Herndon.

FACTUAL BACKGROUND

Background of the Case

8. At all relevant times, Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold Pradaxa® (dabigatran etexilate mesylate).

9. Pradaxa® is a direct thrombin inhibitor that is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Patients with atrial fibrillation have an increased risk of stroke.

10. Pradaxa® was approved by the Food and Drug Administration ("FDA") on October 19, 2010. The FDA approved two dosages: 75 mg and 150 mg, to be taken twice daily. Pradaxa® was the first anticoagulation medication approved in the U.S. in more than 50 years for patients with non-valvular atrial fibrillation.

11. Prior to the FDA's approval of Pradaxa®, warfarin (sold under the brand name Coumadin®) was the only oral anticoagulation available in the U.S. for reducing stroke and systemic embolism in patients with atrial fibrillation. Unlike patients who use Pradaxa®, users of warfarin must follow dietary restrictions and regularly monitor their blood levels (INR) by undergoing blood tests and potentially adjusting the dose of their medication.

Defendants' Over Promotion of Pradaxa®

12. Defendants promoted Pradaxa® as a novel medicine for patients with non-valvular atrial fibrillation. Defendants' marketing campaign for Pradaxa® included promoting it as being more effective than warfarin in preventing stroke and systemic embolism, providing a convenient alternative to warfarin therapy because it does not require blood monitoring or dose adjustments, and does not require any dietary restrictions.

13. Defendants spent significant money in promoting Pradaxa®, which included $67,000,000.00 spent during 2010 (although Pradaxa® was not approved for sale until October 19, 2010).[1]

14. During 2011, Defendants reportedly undertook 1.5 million Pradaxa® "detailing sessions" (marketing/sales visits by Defendants' sales force) with U.S. primary care physicians, internists, group practitioners, cardiologists, and practice nurses, spending approximately $464,000,000.00 during this 12 month period to promote Pradaxa® in the United States.[2]

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[1] Deborah Weinstein, *Study: Sales Support is Dwindling, Not Dead*, March 14, 2012, Medical Marketing and Media.
[2] *Id.*

15. As part of their marketing of Pradaxa®, Defendants widely disseminated direct- to-consumer advertising campaigns that were designed to influence patients, including Plaintiff, to make inquiries to their prescribing physician about Pradaxa® and/or request prescriptions for Pradaxa®.

16. In the course of these direct to consumer advertisements, Defendants overstated the efficacy of Pradaxa® with respect to preventing stroke and systemic embolism, failed to adequately disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa®, and that such irreversibility could have permanently disabling, life-threatening and fatal consequences.

17. Prior to Plaintiff's prescription of Pradaxa®, Plaintiff became aware of the promotional materials described herein.

18. Prior to Plaintiff's prescription of Pradaxa®, Plaintiff's prescribing physician received promotional materials and information from sales representatives of Defendants that Pradaxa® was more effective than warfarin in reducing strokes in patients with non-valvular atrial fibrillation and was more convenient, without also adequately informing prescribing physicians, including Plaintiff's prescribing physician, that there was no reversal agent that could stop or control bleeding in patients taking Pradaxa®.

19. At all times relevant to this action, Defendants also failed to warn emergency room doctors, surgeons and other critical care medical professionals that unlike generally-known measures taken to treat and stabilize bleeding in users of warfarin, there is no effective agent to reverse the anticoagulation effects of Pradaxa®, and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Pradaxa®.

20. At all times relevant to this action, The Pradaxa® Medication Guide, prepared and distributed by Defendants and intended for U.S. patients to whom Pradaxa® has been prescribed, failed to warn and disclose to patients that there is no agent to reverse the anticoagulation effects of Pradaxa® and that if serious bleeding occurs, it may be irreversible, permanently disabling, and life-threatening.

21. From October 2010 until the end of March 2011, approximately 272,119 prescriptions for Pradaxa® were written in the United States. During that same period, there were 932 Pradaxa®- associated "Serious Adverse Event" ("SAE") Medwatch reports filed with the U.S. Food and Drug Administration, including at least 120 deaths and over 500 reports of severe, life-threatening bleeding.

22. From April 1, 2011 until the end of June 2011, there were an additional 856 Pradaxa®- associated "SAE" Medwatch reports filed with the U.S. Food and Drug Administration, including at least 117 deaths and over 510 reports of severe, life-threatening bleeding.

23. During the Defendants' 2011 fiscal year, worldwide Pradaxa® sales eclipsed the $1 billion threshold, achieving what is commonly known in the pharmaceutical industry as "blockbuster" sales status.[3]

24. Defendants' original labeling and prescribing information for Pradaxa®:

a. failed to disclose in the "Warnings" Section that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa®;

b. failed to advise prescribing physicians, such as the Plaintiff's physician, to instruct patients that there was no agent to reverse the anticoagulant effects of Pradaxa®;

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[3] Heide Oberhauser-Aslan and Tapan Sharma, *Boehringer Sees Sales Rising Further as 2011 Profits Surge*, April 24, 2012 WSJ.com.

c. failed to investigate, research, study and consider, fully and adequately, patient weight as a variable factor in establishing recommended dosages of Pradaxa®;

d. failed to investigate, research, study and define, fully and adequately, the safety profile of Pradaxa®;

e. failed to provide adequate warnings about the true safety risks associated with the use of Pradaxa®;

f. failed to warn that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Pradaxa®;

g. failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Pradaxa®;

h. failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Pradaxa® and to continue testing and monitoring of renal functioning periodically while the patient is on Pradaxa®;

i. failed to provide adequate warnings and information related to the increased risks of bleeding events associated with aging patient populations of Pradaxa® users;

j. failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Pradaxa®, especially, in those patients with a prior history of gastrointestinal issues;

k. failed to include a **"BOXED WARNING"** about serious bleeding events associated with Pradaxa®;

l. failed to include a **"Bolded Warning"** about serious bleeding events associated with Pradaxa®; and

m. in their "Medication Guide" intended for distribution to patients to whom Pradaxa® has been prescribed, Defendants failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa® and that if serious bleeding occurs, such irreversibility could have permanently disabling, life-threatening or fatal consequences.

25. During March, 2011, Defendants modified the U.S. labeling and prescribing information for Pradaxa®, which included additional information regarding the use of Pradaxa® in patients taking certain medications. Despite being aware of: (i) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) almost 1,800 SAE Medwatch reports filed with the U.S. Food and Drug Administration, including at least 237 deaths and over 1,000 reports of severe, life- threatening bleeding, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraph 24 (a – m).

26. On July 1, 2011, Pradaxa® was approved for sale in New Zealand with lower dosing (lowered from 150mg to 110mg twice a day) required for patients over 80 years of age and recommended for patients with moderate renal impairment.

27. On July 25, 2011, the Archives of Internal Medicine published The Use of Dabigatran[Pradaxa®] in Elderly Patients. [Vol 171, No. 14], which concluded that "The risk of major overdosage of…[Pradaxa®] in this [elderly] population is, however, much increased owing to frequent renal function impairment, low body weight, drug interactions that cannot be detected with a routine coagulation test and no antagonist available."

28. On January 21, 2011, Pradaxa® (under the brand name Prazaxa®), in 75mg and 110mg doses only, is approved for sale in Japan to treat non-valvular atrial fibrillation.

29. On August 11, 2011, Japan's pharmaceutical regulatory authority announced that it was requiring a **"BOXED WARNING"** be added to Pradaxa® (marketed as Prazaxa® in Japan) to call attention to reports of severe hemorrhages in patients treated with Pradaxa® (Prazaxa®).

30. On September 1, 2011, the New Zealand pharmaceutical regulatory authority issued a "Prescriber Update" entitled "Dabigatran – Is there a Bleeding Risk" in which physicians were alerted that Pradaxa® had a higher incidence of gastrointestinal bleeds than warfarin and that there was no reversal agent to neutralize the anticoagulation effects of Pradaxa®. A follow-up report issued in December 2011, indicated that among 10,000 New Zealanders who had taken Pradaxa®, there were 78 reports of serious bleeding events associated with Pradaxa®, including 60 reports of gastrointestinal and rectal bleeding. Among the 78 serious events were 10 patient deaths and 55 hospitalizations. Three months later in March, 2012 the New England Journal of Medicine published two letters from physicians in New Zealand addressing bleeding events associated with Pradaxa®. In one letter, physicians wrote, "We are concerned that the potential risks of this medication are not generally appreciated. The serious consequences of a lack of an effective reversal agent should not be underestimated."

31. During November, 2011, Defendants modified the U.S. labeling and prescribing information for Pradaxa® adding additional information regarding the use of Pradaxa® in patients with kidney disease despite being aware of: (i) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) the July 25, 2011 article in the Archives of Internal Medicine; (iii) the addition of a **"BOXED WARNING"** to Pradaxa® in Japan; and, (iv) the questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraph 24 (a – m).

32. On December 7, 2011, the U.S. Food and Drug Administration issued a Drug Safety Communication announcing that it was undertaking a "Drug Safety Review" of Post-Marketing Reports of Serious Bleeding Events with the anticoagulant Pradaxa. The purpose of the FDA's review is to determine if serious bleeding events associated with the use of Pradaxa® are more common than

expected based on the Defendants' data submitted to the FDA.

33. As of December 31, 2011, the U.S. Food and Drug Administration received over 500 reports of deaths of people in the U.S. linked to Pradaxa® which, at that point, had been available in the U.S. for approximately 14 months. In addition, there were over 900 reports of gastrointestinal hemorrhages, over 300 reports of rectal hemorrhages, and over 200 reports of cerebrovascular accidents suffered by U.S. citizens associated with Pradaxa®.

34. In January, 2012, the Defendants modified the U.S. labeling and prescribing information for Pradaxa®. Despite being aware of: (i) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) the July 25, 2011 article in the Archives of Internal Medicine; (iii) the addition of a **"BOXED WARNING"** to Pradaxa® in Japan; (iv) the questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®; and (v) the Drug Safety Communication published by the FDA in December, 2011, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraph 24 (a – m).

35. During March 2012, in response to a directive from Health Canada, the governmental agency responsible for regulating pharmaceuticals in Canada, the Defendants' Canadian affiliate issued a "Dear Healthcare Provider" letter in which it advised Canadian healthcare providers of certain risks associated with the use of Pradaxa® (marketed as Pradax® in Canada) in elderly patients and patients with impaired kidney function and prosthetic heart valves. No such similar communication was sent to healthcare providers in the United States.

36. In April 2012, the Defendants modified the U.S. labeling and prescribing information for Pradaxa®. Despite being aware of: (i) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) the July 25, 2011 article in the Archives of Internal Medicine; (iii) the addition of a **"BOXED WARNING"** to Pradaxa® in Japan; (iv) the questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®; (v) the Drug Safety Communication published by the FDA in December, 2011; and (vi) the "Dear Healthcare Provider" letter Defendants were required to provide in Canada, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in ¶¶ 24 (a – m).

37. At all times relevant to this action, Defendants failed to warn emergency room doctors, surgeons and other critical care medical professionals that unlike generally-known measures taken to treat and stabilize bleeding that occurs in the presence of warfarin, there is no effective agent to reverse the anticoagulation effects of Pradaxa® and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Pradaxa®.

Plaintiff's Plaintiff's Use of Pradaxa® and Resulting Injuries

38. As a result of Defendants' claims regarding the effectiveness, safety, and benefits of Pradaxa®, Plaintiff and her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence that Plaintiff would be exposed to the risk of excessive and/or uncontrollable bleeding and the other risks and injuries described herein.

39. Therefore, on or about November 14, 2011 , Plaintiff was prescribed Pradaxa® 150mg, twice a day for treatment of non-valvular atrial fibrillation. On or about September 11, 2014, the Plaintiff was hospitalized at East Alabama Medical Center, in Opelika, Alabama, for a period of approximately six (6) days, suffering from a severe gastrointestinal bleed. As a result of the severe

gastrointestinal bleed, Plaintiff received three (3) units of packed red blood cells. She also underwent an esophagogastroduodenoscopy (EGD) and colonoscopy as a result of the bleed.

40. Prior to Plaintiff's use of Pradaxa®, Defendants knew or should have known that the original labeling of the drug did not adequately warn of the risks associated with using the drug as described above.

41. Prior to Plaintiff's use of Pradaxa®, Defendants knew or should have known of the defective nature of Pradaxa® and persons who were prescribed and ingested Pradaxa® for even a brief period of time, including Plaintiff, were at increased risk for developing life-threatening bleeds. Defendants, through their affirmative misrepresentations and omissions, concealed from Plaintiff's physicians the true and significant risks associated with Pradaxa® use.

42. Plaintiff was unaware of the increased risk for developing life-threatening injuries as compared to warfarin. Had Plaintiff and/or her prescribing physician known of the risks and dangers associated with Pradaxa®, as well as the lack of additional benefits, and had Defendants provided adequate warnings that there is no agent to reverse the anticoagulation effects of Pradaxa®, Plaintiff would not have used Pradaxa®.

43. As a direct and proximate result of using Pradaxa®, Plaintiffs suffered grievous bodily injuries and consequent economic and other losses, including severe mental and physical pain and suffering, loss of enjoyment of life, medical expenses, and loss of consortium, all resulting from Plaintiff's ingestion of Pradaxa.

FIRST CLAIM FOR RELIEF

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against All Defendants)

44. Plaintiffs incorporate by reference paragraphs 1 through 43 of this Complaint, as though set forth in their entirety in this claim for relief and further alleges as follows:

45. At all times relevant to this action, Defendants, and each of them, engaged in the business of designing, manufacturing, testing, marketing, labeling and placing into the stream of commerce Pradaxa® for sale to, and use by, members of the public.

46. At all times relevant to this action, the dangerous propensities of Pradaxa® were known to Defendants or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective product, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

47. The Pradaxa® manufactured and distributed by Defendants reached Plaintiff without substantial change and was ingested as directed.

48. Defendants marketed Pradaxa® in multiple ways, including but not limited to direct-to-consumer advertisements, which were misleading in that Defendants overstated the safety and efficacy of Pradaxa® and understated its risks.

49. The Pradaxa® was defective or unreasonably dangerous in that the labeling was insufficient to adequately warn physicians and users of the increased risk of excessive and/or uncontrollable bleeding.

50. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiff was exposed to Pradaxa®, causing her grievous bodily injuries and consequent economic and other losses, including severe mental and physical pain and suffering, loss of enjoyment of life, and medical expenses, all resulting from Plaintiff's ingestion of Pradaxa®.

51. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

SECOND CLAIM FOR RELIEF

STRICT PRODUCTS LIABILITY – DESIGN DEFECT, MARKETING DEFECT, CONSTRUCTION OR COMPOSITION DEFECT AND MANUFACTURING DEFECT

(Against All Defendants)

52. Plaintiffs incorporate by reference paragraphs 1 through 51 of this Complaint, as though set forth in their entirety in this claim for relief and further alleges as follows:

53. Pradaxa® was unreasonably defective in design and marketing, considering the utility of the product and the risk involved in its use, because as designed and marketed the risks of bleeding associated with the use of Pradaxa®, greatly outweighed its benefits, if any.

54. Pradaxa® was defective in design or formulation in that when it was placed in the stream of commerce by Defendants, it was unreasonably dangerous to an extent beyond that which could reasonably be contemplated by Plaintiff or her physicians. The evidence will establish that any benefit of this drug was outweighed by the serious and undisclosed risks of its use when prescribed and used in the manner intended by Defendants herein. Moreover, the evidence will establish that the Pradaxa® administered to Plaintiff was defective at the time it was distributed by the Defendants or left their control.

55. The evidence will establish that the defective or unreasonably dangerous design and marketing of Pradaxa® was a direct, proximate and producing cause of Plaintiff's injuries and damages. Pursuant to the provisions of the Restatement (Second) of Torts, Defendants are also liable to Plaintiff for all damages claimed in this case, including punitive damages.

56. As a direct, legal, proximate, and producing result of the defective and unreasonably dangerous condition of Pradaxa®, Plaintiffs suffered personal injuries, economic and non-economic damages, including pain, suffering, loss of consortium, and loss of enjoyment of life.

57. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

THIRD CLAIM FOR RELIEF

NEGLIGENCE

(Against All Defendants)

58. Plaintiffs incorporate by reference paragraphs 1 through 57 of this Complaint, as though set forth in their entirety in this claim for relief and further alleges as follows:

59. At all relevant times to this action, Defendants, and each of them, owed a duty to the general public and specifically to Plaintiffs to exercise reasonable care in the design, study, development, manufacture, promotion, sale, labeling, marketing and

distribution of Pradaxa®.

60. Defendants breached their duty and failed to exercise reasonable care in the developing, testing, designing, and manufacturing of Pradaxa® because it was capable of causing serious personal injuries, such as those suffered by Plaintiff, during foreseeable use.

61. Defendants breached their duty and also failed to exercise reasonable care in the marketing of Pradaxa® because they failed to warn that, as designed, Pradaxa® was capable of causing serious personal injuries, such as those suffered by Plaintiff during foreseeable use.

62. Defendants breached their duty and also failed to exercise ordinary care in the labeling of Pradaxa® and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Pradaxa®. Moreover, Defendants over-promoted the benefits of Pradaxa® for anticoagulation therapy in patients suffering from atrial fibrillation and understated the risk of excessive and/or uncontrollable bleeding.

63. Defendants breached their duty and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Plaintiff:

a. In disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

b. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Pradaxa®;

c. Failing to design and/or manufacture a product that could be used safely due to the lack of a known reversal agent; and

d. In designing, manufacturing, and placing into the stream of commerce a product that was unreasonably dangerous for its reasonably foreseeable use, which Defendants knew or should have known could cause injury to Plaintiff.

64. Despite the fact that Defendants knew or should have known that Pradaxa® posed a serious risk of bodily harm and death to consumers and/or did not provide any additional benefits, Defendants continued to manufacture and market Pradaxa® for use by consumers.

65. Defendants knew or should have known that consumers, including Plaintiff would foreseeably suffer injury or death as a result of Defendants' failure to exercise ordinary care as described above.

66. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, labeling, and/or manufacturing of Pradaxa® was a proximate cause of Plaintiffs' injuries and damages.

67. Defendants' conduct as described above, including but not limited to its

failure to adequately test Pradaxa®, to provide adequate warnings, and its continued manufacture, sale and marketing of the product when it knew or should have known of the serious health risks it created, evidences actions and/or intentional disregard of the rights of Plaintiff so as to warrant the imposition of punitive damages.

FOURTH CLAIM FOR
RELIEF BREACH OF
EXPRESS WARRANTY
(Against All Defendants)

68. Plaintiffs incorporate by reference paragraphs 1 through 67 of this Complaint, as though set forth in their entirety in this claim for relief and further alleges as follows:

69. Defendants expressly warranted, through their direct-to-consumer marketing, label, and sales representatives, that Pradaxa® was a safe and effective prescription anticoagulant medication. The safety and efficacy of Pradaxa® constitute a material fact in connection with the marketing, promotion, and sale of Pradaxa®.

70. Pradaxa® manufactured and sold by Defendants did not conform to these express representations because it was not safe and effective for its intended use, and instead caused serious injury to consumers when taken in recommended dosages.

71. As a direct and proximate result of Defendants' breach of warranty, Plaintiffs suffered grievous bodily injuries and consequent economic and other losses, including severe mental and physical pain and suffering, loss of enjoyment of life, medical expenses, and loss of consortium all resulting from Plaintiff's ingestion of Pradaxa®.

72. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions and/or intentional disregard of Plaintiff's rights so as to warrant the imposition of punitive damages.

FIFTH CLAIM FOR RELIEF BREACH OF IMPLIED WARRANTY

(Against All Defendants)

73. Plaintiffs incorporate by reference paragraphs 1 through 72 of this Complaint, as though set forth in their entirety in this claim for relief and further alleges as follows:

74. At the time Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released Pradaxa® into the stream of commerce, Defendants knew of the use for which Pradaxa® was intended and impliedly warranted the product to be of merchantable quality and safe for its intended use and purpose.

75. Plaintiff reasonably relied upon Defendants' skill and judgment as to whether Pradaxa® was of merchantable quality and safe and effective for its intended use and purpose, and reasonably relied upon Defendants' implied warranty as to such matters.

76. Defendants breached their implied warranties of the Pradaxa® product sold to Plaintiff because this product was not fit for its common, ordinary, and intended use, in that the product was unreasonably dangerous when used as directed for its intended purpose as described in this Complaint.

77. As a direct, foreseeable and proximate result of Defendants' breaches of implied warranties, Plaintiffs suffered grievous bodily injuries and consequent economic

and other losses, including severe mental and physical pain and suffering, loss of enjoyment of life, medical expenses, and loss of consortium all resulting from Plaintiff's ingestion of Pradaxa®.

78. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions and/or intentional disregard of Plaintiff's rights so as to warrant the imposition of punitive damages.

SIXTH CLAIM FOR RELIEF

NEGLIGENT MISREPRESENTATION AND/OR FRAUD

(Against All Defendants)

79. Plaintiffs incorporate by reference paragraphs 1 through 78 of this Complaint, as though set forth in their entirety in this claim for relief and further alleges as follows:

80. Defendants, in the course of its business profession, knowingly and negligently supplied Plaintiff's physicians with false information through Defendants' written literature and representations by sales agents for guidance in the physicians' and the patient's decision to use and/or approve Pradaxa®.

81. Defendants represented that Pradaxa® was just as safe or safer and as effective or more effective than other anticoagulation alternatives and had additional

benefits compared to other anticoagulation medications available on the market.

82. Defendants made these misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that Pradaxa® had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff and the health care industry generally. Specifically, Defendants misrepresented to and/or actively concealed from the consuming public, among other things, that:

a. Pradaxa® had statistically significant increases in irreversible bleeds and other side effects which could result in serious, permanent injury or death;

b. Pradaxa® had not been fully or adequately tested;

c. Pradaxa® does not have any known reversal agents;

d. Pradaxa® bleeds cannot be stopped or controlled by any effective medical processes or medical intervention;

e. Failed to warn that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Pradaxa®; and

f. Pradaxa® was not as safe as blood thinners such as warfarin.

83. Defendants negligently and/or intentionally misrepresented or omitted this information in their product labeling, promotions and advertisements and instead labeled, promoted and advertised their product as safer and more effective than other types of

anticoagulation alternatives, and understated the risk of excessive and/or uncontrollable bleeding associated with Pradaxa®.

84. The aforementioned misrepresentations were untrue and misleading.

85. Defendants knew or should have known that these representations were false and made the representations with the intent that Plaintiff and/or her prescribing physicians would rely on them, leading to the use of Pradaxa®.

86. In willfully supplying the false information, Defendants negligently failed to exercise reasonable care in obtaining or communicating information to Plaintiff and her physicians.

87. At the time of Defendants' fraudulent misrepresentations, Plaintiff and/or her prescribing physicians were unaware of the falsity of the statements being made and believed them to be true. Plaintiff and/or her prescribing physicians justifiably relied on and/or were induced by the misrepresentations and/or active concealment, and relied on the absence of safety information, which Defendants did suppress, conceal or failed to disclose, to Plaintiff's detriment.

88. The false information obtained and communicated by Defendants to Plaintiff's physicians was material and upon which the medical community justifiably relied in good faith to their detriment.

89. As a direct and proximate result of the fraudulent acts and omissions, and

misrepresentations of Defendants, Plaintiffs suffered injuries, economic and non-economic damages, including pain and suffering, loss of enjoyment of life, and loss of consortium.

90. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions and/or intentional disregard Plaintiff's rights so as to warrant the imposition of punitive damages.

SEVENTH CLAIM FOR RELIEF

FRAUD AND INTENTIONAL MISREPRESENTATION

(Against All Defendants)

91. Plaintiffs incorporate by reference paragraphs 1 through 90 of this Complaint, as though set forth in their entirety in this claim for relief and further alleges as follows:

92. Defendants knowingly, willfully, and intentionally made material, false, fraudulent, and misleading misrepresentations through their written literature and through their sales representatives to Plaintiff, his physician and to the public that Pradaxa® was safe for its prescribed use and that Defendants' labeling, marketing and promotion fully and adequately described, informed, and warned of all known risks of the product.

93. Defendants' misrepresentations were in fact false and fraudulent, as Pradaxa® is not safe for its intended use and it's labeling, marketing, and promotion did not adequately describe, inform, or warn the medical community and patients of all known risks of the product.

94. Defendants had or should have had actual knowledge and information based upon studies, published reports, and clinical experience that its product Pradaxa® created an

unreasonable risk of serious bodily injury and death to consumers, when used by patients as directed by Defendants.

95. Defendants knowingly, willfully, and intentionally concealed the true information regarding the risks of harm created by their product in the product labeling, marketing, and promotion

and instead, labeled, promoted and marketed their product as safe for use in order to avoid monetary losses and in order to sustain profits in sales to consumers.

96. When Defendants made these misrepresentations that Pradaxa® was safe and effective for its intended use, Defendants knowingly, willfully, and intentionally concealed and withheld from Plaintff, her physicians, and the public the true facts known by Defendants that Pradaxa® is not safe for its intended and prescribed use and purpose.

97. Defendants had a duty to disclose to Plaintiff and her physicians that Pradaxa® was not safe in that it can cause serious uncontrollable bleeding events and death, because Defendants had superior knowledge of these facts that were material to Plaintiff and her physicians' decision to use Pradaxa®.

98. Plaintiff and her physician reasonably and justifiably relied upon Defendants' intentional concealment of the true facts, and reasonably and justifiably relied upon Defendants' misrepresentations to Plaintiff and her health care providers that Pradaxa® was safe and that Defendants' labeling, marketing and promotion fully and adequately described, warned, and informed all known risks of the product.

99. Had Plaintiff and her physicians known of Defendants' intentional and fraudulent concealment of the true facts that Pradaxa® was not safe for human use, Plaintiff's healthcare providers would not have prescribed Plaintiff with Pradaxa® and Plaintiff would not have agreed to have used Pradaxa® as directed by Defendants.

100. As a direct and proximate result of Defendants' fraudulent misrepresentations and intentional concealment, Plaintiffs suffered grievous bodily injuries as well as other severe mental and physical pain and suffering, loss of enjoyment of life, medical expenses, and loss of consortium all resulting from Plaintiff's ingestion of Pradaxa®.

101. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions and/or intentional disregard of Plaintiff's rights so as to warrant the imposition of punitive damages.

EIGHTH CLAIM FOR
RELIEF STRICT
LIABILITY IN TORT
(Against All Defendants)

102. Plaintiffs incorporate by reference paragraphs 1 through 101 of this Complaint, as though set forth in their entirety in this claim for relief and further alleges as follows:

103. Defendants manufactured, sold, used, and controlled the toxic Pradaxa® substance for use in humans.

104. Pradaxa® is highly toxic, inherently dangerous, and ultra-hazardous to humans.

105. Defendants allowed and directed that toxic Pradaxa® be used and in humans.

106. As a direct and proximate result of Defendants' use and control of toxic Pradaxa®, toxic Pradaxa® was administered and released into the body of Plaintiff; and as a proximate result of Defendants' conduct and actions, Plaintiff suffered serious physical injuries and death.

107. Defendants' actions and conduct are the proximate cause of Plaintiff's damages and Defendants are strictly liable under applicable law for Plaintiffs' injuries, damages, and losses.

NINTH CLAIM FOR
RELIEF GROSS
NEGLIGENCE
(Against All Defendants)

108. Plaintiffs incorporate by reference paragraphs 1 through 107 of this Complaint, as though set forth in their entirety in this claim for relief and further alleges as follows:

109. Plaintiff would further show that the negligent acts and/or omissions of

Defendants, as set forth above, constitute an entire want of care so as to indicate that the acts and/or omissions in question were the result of conscious indifference and/or malice so as to give rise to the award of exemplary damages.

110. Plaintiff would further show that the negligent acts and/or omissions of Defendants, as set forth above, constitute an act or omission,

a. which, when viewed objectively from the standpoint of Defendants, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to Plaintiff, and

b. of which Defendants had actual, subjective awareness of the risks involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of Plaintiff.

111. The gross negligence of the Defendants was a proximate cause of the injuries and damages suffered by Plaintiffs.

TENTH CLAIM FOR
RELIEF LOSS OF
CONSORTIUM
(Against All Defendants)

112. Plaintiffs incorporate by reference paragraphs 1 through 111 of this Complaint, as though set forth in their entirety in this claim for relief and further alleges as follows:

113. Plaintiff, James M. Barbaree, was at all times relevant hereto the spouse of Plaintiff, Mary Loyd Barbaree and is currently her caretaker.

114. For the reasons set forth herein, Plaintiff has been caused, presently and in the future, to suffer the loss of companionship and society of his spouse, and accordingly, the Plaintiff has been caused great mental anguish.

ELEVENTH CLAIM

FOR RELIEF

PUNITIVE DAMAGES

(Against All Defendants)

115. Plaintiffs incorporate by reference paragraphs 1 through 114 of this Complaint, as though set forth in their entirety in this claim for relief and further alleges as follows:

116. The acts, conduct, and omissions of Defendants were willful and malicious and were done with a conscious disregard for the health, safety, and rights of Plaintiff, and other foreseeable users of the pharmaceutical agents identified in this Complaint, and for the primary purpose of increasing Defendants' profits from the sale and distribution of their drug product, Pradaxa®. The outrageous and unconscionable conduct of Defendants, as set forth herein, warrants an award of exemplary and punitive damages against Defendants, and each of them in an amount appropriate to punish and make an example of each Defendant.

117. Prior to the manufacturing, sale and distribution of Pradaxa®, Defendants

knew that Pradaxa® was in a defective condition as previously described herein and knew that those who were prescribed and the foreseeable users who took them would experience and did experience severe and permanent physical, mental, and emotional and economic injuries. Further, Defendants, through their officers, directors, managers and agents, had knowledge that Pradaxa® presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and, as such, said purchasers and/or consumers of Pradaxa® were unreasonably subjected to risk of a serious bleeding event from the consumption of said drug.

118. Despite such knowledge, Defendants, acting through their officers, directors and managing agents for the purpose of enhancing their profits, knowingly and deliberately failed to remedy the known defects of Pradaxa® and failed to warn any and all persons who prescribed, purchased or consumed Defendants' anticoagulation drug product, including but not limited to, any and all physicians and foreseeable users of Pradaxa®, of the extreme and dangerous risks associated with the foreseeable uses of their pharmaceutical product and its defective nature. Defendants, as well as their individual agents, officers, and directors intentionally proceeded with the manufacturing, packaging, labeling, distribution, marketing and sale of Pradaxa® knowing that foreseeable users would be exposed to serious potential danger in order to advance Defendants' own pecuniary interest and monetary profits. The conduct of Defendants, and each of them, was despicable, and so contemptuous that it would be looked down upon and despised by

ordinary decent people, and carried on by Defendants with willful and conscious disregard for the safety of Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, prays for relief on the entire Complaint, as follows:

a. Judgment be entered against all Defendants on all claims of relief of this Complaint;

b. Actual damages as alleged, jointly and/or severally against Defendants, in excess of

$75,000;

c. Pain and suffering;

d. Loss of enjoyment of life;

e. Medical expenses;

f. Loss of consortium, companionship and society;

g. Punitive damages alleged against Defendants, including Plaintiff's attorneys' fees, in excess of $75,000;

h. Costs of court and reasonable attorney fees necessary for preparation of this case for trial;

i. Prejudgment interest at the highest legal rate allowed by law;

j. Interest on the judgment at the highest legal rate from the date of judgment until collected; and

k. Such other relief the Court deems as just and appropriate.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated this 8th day of September, 2015

RESPECTFULLY SUBMITTED,

/s/ Ronnie G. Penton
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